

### III. REMARKS

#### A. Status of the Claims

Claims 1-3 and 5-11 were pending in this application, and all claims were rejected.

Claims 1, 3, 5, 10 and 11 are amended herein. The foregoing claim amendments were made solely in an effort to expedite prosecution and allowance of the present application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

New claims 12-20 are added to more particularly claim the invention. Support for new claims 12-20 are found at least, for example, in the specification on page 4, lines 19-20; in Example 1; and in the original claims.

Applicant believes that *no new matter has been added* to the claims by these amendments. Accordingly, upon entry of the present amendment and response, claims 1-3, and 5-20 will be pending.

Applicant acknowledges with appreciation the Examiner's withdrawal of the previous:

- objections to the specification; the objection/rejection of claims 2, 7 and 8;
- rejection of claims 1-2, 5-7 and 9 under 35 USC §102 (b) as allegedly anticipated by *Scholz*;
- rejection of claims 1-3, 6 and 9 under 35 USC §102 (b) as allegedly anticipated by *DePhilips*; and
- rejection of claims 1-3 and 5-9 under 35 USC §102 (b) as allegedly anticipated by *Ramage*.

#### B. 35 U.S.C. §112 First Paragraph Rejection

Claims 10-11 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In view of the foregoing claim amendments, Applicant respectfully submits that the charge density of the ionic adsorbent encompassed by

claims 10-11 are described by the originally filed specification and, accordingly, request reconsideration and withdrawal of this rejection.

**C. 35 U.S.C. §112 Second Paragraph Rejections**

Claims 1-3 and 5-11 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses this rejection.

Applicant has amended claim 1, in part, to more clearly express a method of separating a selected ionic component from a sample using an ionic adsorbent in the absence of an additional salt that binds with the ionic adsorbent comprising the steps of contacting the sample containing the selected ionic component with an ionic adsorbent having a charge density that selectively binds to the selected ionic component.

Applicant submits that claims 1-3 and 5-11 meet the specific requirements of 35 U.S.C. §112, second paragraph, and respectfully requests reconsideration and withdrawal of this rejection.

**D. 35 U.S.C. §102 Rejection**

Claims 1, 2, 4, 6 and 9-11 remain rejected under 35 U.S.C. §102 (b) as allegedly anticipated by *Wu, D. et al.*, "Effects of Stationary Phase Ligand Density On High-performance Ion-exchange Chromatography of Proteins", Journal of Chromatography 598, 7-13, 1992, (hereinafter, "*Wu*"). Applicant respectfully traverses for at least the following reasons.

Applicant notes that claim 4 was previously cancelled in the Response dated November 17, 2007.

The standard for anticipation is one of strict identity and "the reference must teach every aspect of the claimed invention either explicitly or inherently." (MPEP §706.02 IV, lines 6-7) Additionally, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131.

Applicant's claimed invention as taught throughout the specification, see for example paras [0008] to [0017], is directed to a method of separating a selected ionic component from a sample by contacting the sample with an ionic adsorbent whose charge density is such that the component is bound selectively in the absence of added ionic component (salt) that competitively binds the adsorbent. Applicant has found a method of separating selected ionic components from a sample by varying the charge density of binding surfaces of an ionic adsorbent, without using an added salt in the sample as typically used in the art. The invention bypasses the need for the inclusion of competing ionic components (e.g. salts) in the sample comprising the selected ionic component while providing a highly selective method of separation. Selectivity is achieved by using an ionic adsorbent of a predetermined charge density suitable for selective binding of the ionic component of interest over a range of ionic strengths. Thus, a sample may be brought directly into contact with the adsorbent, without any costly pretreatment of the sample, since the use of large quantities of additional salts is no longer necessary.

*Wu* teaches cation-exchange matrices having variable ligand densities attached thereto (stationary phase) used in high-performance ion-exchange chromatography of proteins (e.g., lysozymes and cytochrome c). High-performance ion-exchange chromatography was performed to isolate these proteins, but always in the presence of one or two additional ionic components (e.g., Na<sup>+</sup> salts present in either solution A or B) that also bind to the ionic adsorbent. (see pages 8-9; and Table II).

Applicant asserts that *Wu* fails to teach a method of:

- separating a selected ionic protein component from a sample using an ionic adsorbent in the absence of an additional salt that binds with the ionic adsorbent (Claim 1);
- separating a selected ionic polymeric compound from a sample having at least two ionic polymeric compounds with an ionic adsorbent in the absence of an added second ionic component that binds the adsorbent (Claim 12); and
- separating a selected ionic biomolecule from a sample having at least two ionic biomolecules using an ionic adsorbent in the absence of an additional salt that binds with the ionic adsorbent (Claim 15).

Applicant respectfully contends that the Office Action on page 4, section (1), has mischaracterized *Wu*'s teachings in Figs. 1 and 2, on page 9, but that the claims as currently amended render this rejection moot since *Wu*'s Fig. 1 does not pertain to samples having either a protein component, a ionic polymeric compound, or an ionic biomolecule, and Fig. 2 apparently includes the use of additional salt component (*see* page 8, col. 2).

Applicant also respectfully disagrees with the Office Action's assertion on page 5, section (2), that states:

"Even if Wu did not only show experiments in which there is an added second ionic component that competitively binds the adsorbent, the reference would still anticipate. This is because claim 1 can be read such that the recitation of "in the absence of an added second ionic component that competitively binds the adsorbent" need not refer to the conditions of the claimed method but, rather, as a mere description of how the ionic adsorbent would act under conditions in which there is no added second ionic component that compressively binds the adsorbent".

The MPEP 2173.05(i) [Negative Limitations], states that the current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively.

Applicants assert that the claim recitation "in the absence of an additional salt that binds with the ionic adsorbent" is a claim limitation, albeit a negative one, and not a "mere description of how the ionic adsorbent would act under conditions in which there is no added second ionic component that compressively binds the adsorbent" as alleged in the Office Action.

Applicant also respectfully contends that the claim recitation "in the absence of an additional salt that binds with the ionic adsorbent" is a distinguishing negative limitation which clearly excludes *Wu* as an anticipatory reference to the invention as claimed. Since claims 2, 6 and 9-11 depend from claim 1, Applicant respectfully contends these claims are not anticipated by *Wu* as well, since *Wu* fails to teach each element as set forth in claim 1. As such, Applicant contends that the anticipatory rejection has been rebutted, and respectfully requests reconsideration and withdrawal of this rejection.

#### IV. CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections, and the timely allowance of the pending claims. Applicant believes that the above response is a complete response to the present office action. If however the Examiner believes that some requirement has been missed or not completely answered, the Examiner is invited to contact Applicant's attorney at the number below. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account.

Respectfully submitted,

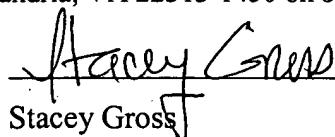


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